UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO *State of Nevada v. American Home Prods. Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR	Civil Action No. 01-CV-12257-PBS Judge Patti B. Saris

LOCAL RULE 56.1 STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF NOVARTIS PHARMACEUTICALS CORPORATION'S MOTION FOR SUMMARY JUDGMENT

Defendant Novartis Pharmaceuticals Corporation ("NPC") respectfully submits the following Statement of Undisputed Facts as to NPC pursuant to Local Rule 56.1. These undisputed facts, and the undisputed facts in Defendants' Joint Local Rule 56.1 Statement of Undisputed Material Facts in Support of Their Joint Motion for Summary Judgment in *State of Nevada v. American Home Prods., Corp.* ("Defs. Joint. Nev. 56.1 stmt"), which NPC incorporates by reference, demonstrate that NPC is entitled to summary judgment on all claims as a matter of law.

A. The Parties

1. Plaintiff Nevada purports to bring claims on behalf of the Nevada Medicaid agency and other third-party payors located in Nevada, asserting that these payors overpaid doctors and pharmacies ("Providers") for prescription drugs dispensed or administered to Medicaid and private insurance beneficiaries. (Nevada Amend. Compl. at ¶ 8.)

2. Defendant NPC is a Delaware corporation with headquarters in East Hanover, New Jersey, that was formed by merger effective January 1, 1997. (Conley Aff. at ¶ 5.)[1] NPC manufactures and markets Brand Name prescription drugs ("Brand Name drugs"). (*Id.* at ¶ 6.) It does not market and sell generic drugs. (*Id.*)

B. The Products at Issue

3. Brand Name drugs bear a unique trade name in addition to the chemical name that identifies their active ingredient. (Declaration of Gregory K. Bell, Ph.D. submitted in support of Defendants' Motions for Summary Judgment ("Bell Decl.") at ¶ 9.) Brand Name drugs are virtually always covered initially by one or more

[1] Michael Conley is Executive Director for U.S. Managed Markets, Trade Corporate Accounts, and Customer Service at NPC. (Conley Aff. at ¶ 1.)

patents. (*Id*.) This means that no other company can make, use, or sell the same product without a license from the patent owner. (*Id*. at ¶ 9, n. 6.)

4. In this action, Brand Name drugs fit into two relevant categories: physician-administered, which must be administered by a health-care professional (usually, either a doctor or a nurse working with a doctor), and self-administered, which patients pick up at pharmacies and take on their own. (*Id*. at ¶¶ 5-7.)

5. A physician-administered drug ("PAD") is purchased by a physician, who then "sells" and administers (or has an assistant administer) the drug to the patient. (*Id*. at ¶ 8.) The physician chooses which drug to administer. (*Id*.)

6. By contrast, a self-administered drug ("SAD") is purchased by a pharmacy and then "sold" to the patient, who takes the drug himself. (*Id*. at ¶ 6-7.) The patient's physician determines which drug the patient takes. (*Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris,* for purposes of the motion for class certification, in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-CV-12257-PBS (D. Mass.) ("Berndt Report") at ¶ 42, attached as ¶ 15, Ex. 5 to (Lonergan Aff; Bell Decl. at ¶ 10.) If the physician prescribes a Brand Name SAD, the pharmacy must dispense that product. (*Id*.) It may not substitute another product, even if the alternative is approved by the U.S. Food and Drug Administration ("FDA") for the same illness or condition. (Bell Decl. at ¶ 10, n. 9.)

7. Because physicians alone determine which Brand Name SADs patients take, pharmacies have little to no influence over a given Brand Name SAD's sales volume. (Berndt Report at ¶ 42, attached as ¶ 15, Ex. 5 to Lonergan Aff.; (Bell

Decl. at ¶ 10.); *In re Brand Name Prescription Drugs Antitrust Litigation*, 186 F.3d 781, 787 (7th Cir. 1999) (Posner, CJ).)

8. Because retail pharmacies cannot influence which Brand Name SADs physicians prescribe, manufacturers generally do not give retail pharmacies discounts on purchases of Brand Name SADs. (*Id.*)

9. Because retail pharmacies cannot influence which Brand Name SADs physicians prescribe, it would not make any sense for NPC to attempt to increase the difference between AWP and acquisition cost (*i.e.*, the "spread") on its drugs to benefit the pharmacies. NPC would also have no reason to increase the "spread" in order to induce physicians to prescribe its single-source SADs, as physicians are not involved in the financial aspects of the transaction. (Bell Decl. at ¶ 10, ¶ 10 n. 11.)

10. The following NPC drugs at issue here are entirely self-administered: Clozaril, Combipatch, Comtan, Diovan, Diovan HCT, Elidel, Estraderm, Exelon, Famvir, Femara, Focalin, Lamisil, Lamprene, Lescol, Lescol XL, Lotensin, Lotensin HCT, Lotrel, Miacalcin SPR, Parlodel, Rescula, Ritalin, Ritalin LA, Starlix, Tegretol, Tegretol XR, Trileptal, Vivelle, Vivelle-DOT, Voltaren Opthalmic, Zaditor, and Zelnorm. (Conley Aff. at ¶ 7.)

11. Through a joint venture with Noven Pharmaceuticals, Inc. called Novogyne Pharmaceuticals, NPC purchased Combipatch from Sanofi-Aventis on March 30, 2001. (Schultz Aff. at ¶ 10.)[2]

12. NPC purchased Famvir from GlaxoSmithKline on December 31, 2000. (*Id.* at ¶ 11.)

[2] Bette Schultz is Vice President for Business Development and Licensing & Mature Products at NPC. (Schultz Aff. at ¶ 1.)

13. The other two NPC drugs at issue here are Miacalcin Injection and Aredia. (Nev. Amend. Compl., Ex. A.)

14. Miacalcin Injection is generally a SAD but may in rare cases be physician-administered, either to demonstrate to a patient how to self-administer the drug or where a patient is either incapacitated or too ill to self-administer the drug. (Schultz Aff. at ¶¶ 3-4.)

15. Miacalcin Injection faced no competition, either brand or generic, until after Nevada filed its first Complaint naming NPC on August 1, 2003. (*Id*. at ¶¶ 6-9.) Because patients prefer to take a tablet or an oral solution rather than to inject themselves with a drug, a physician typically will prescribe Miacalcin Injection only when a patient is medically unable to take a drug indicated for the same condition that comes in tablet or oral solution form. (*Id*. at ¶¶ 7-8.)

16. Aredia is a PAD. (Held Aff. at ¶ 4).[3] Aredia faced no competition, either brand or generic, until July 2001, when NPC introduced Zometa. (*Id*. at ¶ 5.) Aredia faced no competition from a non-NPC drug until December 2001, when a generic version was introduced. (*Id*. at ¶¶ 5, 7.)

17. NPC has not marketed Aredia to physicians since the time NPC introduced Zometa in July 2001. (*Id*. at ¶ 6.)

18. According to drug utilization data reported by Nevada Medicaid and made public by the Centers for Medicare and Medicaid Services, during the period from January 1, 1997, to and including the second quarter of 2003, which is inclusive of the relevant period ending on June 12, 2003, Nevada Medicaid's total outlay for Aredia

[3] Thomas Held was brand director of Aredia at NPC from 1998 to 2002. (Held Aff. at ¶ 1.)

was $1,320.13, an average of $188.59 per year, and for Miacalcin Injection, $14,363.68, an average of $2,051.95 per year. (Lonergan Aff. at ¶ 4.)

C. NPC's Marketing and Sales Methods

19. NPC delivers the vast majority of its products to, and is paid by, wholesalers, who resell them to retail pharmacies, private and public hospitals, and other health care Providers that take possession of drugs and dispense them to patients. (Conley Aff. at ¶ 8; Arena Dep. at 150:9-151:4, attached as ¶ 16, Ex. 6 to Lonergan Aff.) NPC also delivers drugs directly to certain "warehousing retail chains" – drugstore chains of ten or more stores that have their own warehouses that provide wholesaler-type services for the chain. (Conley Aff. at ¶ 8; Arena Dep. at 151:5-17; NPC's Resps. and Objects. to Plaint. Interrog., Req. for Prod. of Docs., and Req. for Admiss. in *State of Nevada v. American Home Prods.* ("NPC's Resps. and Objects.") at 5.) NPC does not deliver products directly to, or take payment from, most physicians, retail pharmacies, or other Providers. (Arena Dep. at 151:5-17; NPC's Resps. and Objects. at 5.)

20. Because physicians choose whether to prescribe an NPC drug or a competing Branded therapeutic alternative, NPC markets its products' benefits to physicians, even though, for most prescriptions (*i.e.*, when they prescribe SADs), physicians do not actually buy the products. (Bell Decl. at ¶ 10; Arena Dep. at 12:22-13:4.) To that end, NPC has a sales force that calls upon physicians in order to provide research and other information about the products, explain their benefits, and answer questions. (Arena Dep. at 12:22-13:4.)

21. NPC markets drugs based primarily on their clinical efficacy and safety. (*Id*. at 20:21-21:4.) NPC's sales representatives do not market to physicians the difference between a drug's AWP and the physician's acquisition cost. (*Id*. at 156:14-

157:6.) Any sales force member who deviates from the authorized message may be terminated. (*Id*. at 69:21-70:4; 70:13-71:13.)

D. NPC's Pricing and Price Reporting

22. NPC generally sells its prescription pharmaceuticals to wholesalers and warehousing retail chains at a price referred to as Wholesale Acquisition Cost ("WAC"), minus a two percent prompt pay discount. (Conley Aff. at ¶ 9.) When NPC launches a new product or changes the price of an existing one, it provides pricing information to wholesalers, warehousing retail chains, and independent price reporting services such as First DataBank by issuing a "broadcast fax." (*Id.* at ¶ 14.) A broadcast fax is essentially a letter under the name of an NPC executive that lists the WAC, Average Wholesale Price ("AWP"), or both for one or more drugs. (*Id.*)

23. Beginning in January 1997, NPC's broadcast faxes that included AWP information also contained the following disclosure:

> As used in this letter, the term AWP or Average Wholesale Price constitutes a reference for each Novartis product, and in keeping with current industry practices, *is set as a percentage above the price at which each product is offered generally to wholesalers*. Notwithstanding, the inclusion of the term price, in Average Wholesale Price, AWP is not intended to be a price charged by Novartis for any product to any customer.

NPC Broadcast Fax, January 31, 1997 (emphasis added). (*Id*. at ¶¶ 15, 16, Ex. 2.) The disclosure's exact wording changed slightly over time; however, the disclosure's central message – that AWP is not intended to reflect a price charged by NPC to anyone – remained constant. (Conley Aff. at ¶ 15.)

24. Consistent with this disclosure, NPC calculated the AWP it reported for any given product by applying a percentage markup to that drug's WAC.

(*Id*. at ¶ 17.) For all but four NPC drugs at issue here, the AWP is equal to WAC plus 20 percent, which, put differently, means that the WAC is equal to AWP minus 16.66 percent. (*Id*.) For Diovan, Diovan HCT, Famvir, and Zaditor, the AWP is WAC plus 25 percent, which, put differently, means that the WAC is equal to AWP minus 20 percent. (*Id*.)

E. First DataBank's AWP and Settlement of Class Action

25. Nevada's Medicaid agency based its reimbursement for pharmaceutical drugs on the AWP published by First DataBank, an independent, third-party publisher. (Nev. Amend. Compl. at ¶ 126; Nevada State Medicaid Plan, Attach. 4.19-B, p. 3.)

26. Patricia Kay Morgan, Manager, Product Knowledge-based Services at First DataBank, has testified that First DataBank during the relevant period published two AWPs for a given pharmaceutical drug: a "Suggested Wholesale Price" reported by the manufacturer, and a "Blue Book" AWP that First DataBank determined independent of what the manufacturer reported and that had "become synonymous with AWP to many of our customers." (Morgan Dep. at 36:3-19, attached as ¶ 17, Ex.7 to Lonergan Aff.) Morgan testified:

> Q. Okay. SWP, what does that refer to?
> A. It's the suggested wholesale price, and it's populated if the manufacturer suggests an AWP.
> Q. Some manufacturers include an AWP on their price lists; is that correct?
> A. A suggested AWP, yes.
> Q. And that's where you put that into what you call the SWP field?
> A. That's correct.
> Q. What is Blue Book price?
> A. Blue Book is what's become synonymous with AWP to many of our customers, so it is the average wholesale price, so it's the price that includes the markup after our wholesaler survey, if the product's available through the wholesaler.

(*Id*.) Morgan also confirmed that First DataBank determined the "Blue Book" AWP used by customers by surveying wholesalers:

> A. I assume you're asking how we determined the markup, is that the question?
> Q. Yes.
> A. We basically contacted the national wholesalers to find out what markup they were applying to a manufacturer's line, or we could to a specific NDC, if necessary, and then that number was entered into a table. And that's pretty much it.
> Q. So you were asking the wholesalers for a markup factor that they applied to a company's products?
> A. Correct.

(Morgan Dep. at 47:8-20.)

27. Beginning in January 2002, First DataBank unilaterally changed the markup factor it used to calculate AWPs for NPC drugs to 25 percent, which had the effect of making First DataBank's reported AWPs higher than NPC's reported AWPs for all NPC drugs at issue here other than Diovan, Diovan HCT, Famvir, and Zaditor. (Conley Aff. at ¶¶ 19-22.)

28. As part of a proposed Settlement Agreement and Release in a separate litigation – to which NPC was not a party – First DataBank has since agreed to change its price-publishing practices; specifically, First DataBank agreed to reduce its "Blue Book" AWP to WAC plus 20 percent for all pharmaceuticals subject to the Settlement, which include NPC drugs. ("Settlement Agreement and Release" in *New England Carpenters Health Benefit Fund, et al v. First DataBank, Inc.*, Civ. Action No. 1:05-CV-11148-PBS (D. Mass.), submitted for court approval on October 4, 2006, at p. 19 (attached as ¶ 19, Ex. 9 to Lonergan Aff.)

F. Nevada's Medicaid Obligations and Objectives

29. Providers voluntarily participate in Medicaid and are therefore free to deny services to Medicaid beneficiaries, just as they are free to deny services to any person. (Defs. Joint. Nev. 56.1 stmt. at ¶ 77.) Under federal law, a state that participates in Medicaid must maintain a State Plan that establishes reimbursement rates that "are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." (*See* 42 U.S.C. §1396a(a)(30)(A); *see also* Defs. Joint Nev. 56.1 stmt. at ¶ 77.)

30. To comply with 42 U.S.C. §1396a(a)(30)(A), Nevada established a reimbursement rate for Brand Name drugs that would offer Providers a sufficient incentive (*i.e.*, profit) to participate in its Medicaid program. (Defs. Joint Nev. 56.1 stmt. at ¶¶ 77, 89.) Nevada reimbursed at a percentage discount off AWP – which Nevada Medicaid knew, since at least 1986, exceeded Providers' acquisition cost. (*Id.* ¶¶ 46-47.) Nevada Medicaid also knew that its AWP-based reimbursement rate exceeded Providers' acquisition cost. (*Id*. at ¶¶ 77; 78-81) Nevada concedes that no regulation governs how AWP should be calculated. (Nev. Sec. Amend. Compl. ¶ 116.)

31. Federal law requires participating pharmaceutical manufacturers, such as NPC, to provide rebates to participating states that are based on utilization of a manufacturer's drug by the patients whose use of the drug is paid for by Medicaid (*i.e.*, the beneficiaries). *See* 42 U.S.C. §1396r-8(a)-(c).

32. Accordingly, NPC has paid rebates to Nevada Medicaid, and those rebates have lowered Nevada's net cost for NPC drugs. (Lonergan Aff. at ¶¶ 5-7.) For each unit of an NPC drug dispensed or administered to a Medicaid beneficiary, NPC has

paid Nevada at least the greater of Average Manufacturer Price ("AMP") multiplied by 15.1 percent or AMP minus Best Price. *See* 42 U.S.C. ¶ 1396r-8(c). During the relevant period, NPC paid Nevada Medicaid rebates totaling $1,838,578.69. (Lonergan Aff. at ¶ 7.)

G. Discounting and Rebating

33. NPC generally provides price concessions in the form of either rebates or discounted prices to entities that control drug formularies, because whether a drug is placed on a formulary can influence patients' preferences and physicians' prescribing decisions. (Conley Aff. at ¶ 10.) When NPC contracts to provide rebates, the purpose is to obtain or maintain a position on the formulary of an entity that typically does not take possession of NPC drugs, such as a state Medicaid agency that has a preferred drug list, pharmaceutical benefits manager, or health maintenance organization. (*Id*. at ¶ 13.) Rebates ultimately lower the entity's net cost for NPC drugs. (*Id*.)

34. By contrast, in order to obtain or maintain a position on the formulary of an entity that purchases and takes possession of NPC drugs, such as a hospital, NPC will negotiate a contract price – typically at a discount off WAC – at which the entity may purchase the NPC drug from a wholesaler. (*Id*. at ¶ 11; NPC's Resps. and Objects. at 6.) When the wholesaler resells the NPC product to the entity at the contract price, NPC provides that wholesaler with what is called a "chargeback," which reimburses the wholesaler for having sold the product to the contract customer at a price below the wholesaler's own cost. (Conley Aff. at ¶¶ 11-12; NPC's Resps. and Objects. at 6.)

35. During the relevant period, NPC provided several Nevada agencies with discounts on purchases of NPC drugs. (Lonergan Aff. at ¶¶ 8-13.) For example, Northern Nevada Adult Mental Health Services ("Northern Nevada") (known until 2001 as the Nevada Mental Health Institute (*see* Senate Bill 540, approved May 30, 2001,[4])) and Southern Nevada Adult Mental Health Services ("Southern Nevada") received contractual discounts on non-Medicaid purchases of NPC drugs. Both are agencies of the Mental Health and Developmental Services Division of the Nevada Department of Health and Human Services, the same department that oversees Nevada Medicaid. (*See* http://mhds.state.nv.us/mh/index.shtml; Defs. Joint Nev. 56.1 stmt. at ¶ 3.) Northern Nevada received contractual discounts on six NPC drugs at issue here. During the relevant period, Northern Nevada's cost of acquiring these drugs was 89.2 percent of the amount that Nevada Medicaid reimbursed Providers for these same drugs, net of dispensing fees. (Lonergan Aff. at ¶ 10.) Southern Nevada received contractual discounts on six NPC drugs at issue here. During the relevant period, Southern Nevada's cost of acquiring these six drugs was 85.6 percent of the amount that Nevada Medicaid reimbursed Providers for these same drugs, net of dispensing fees. (*Id*. at ¶ 14.) The percentage is based on weighted averages of Northern Nevada and Southern Nevada's purchase costs, and Nevada Medicaid's reimbursements, for the drugs during the relevant period. (*Id*. at ¶¶ 10, 14.) The purchase data is weighted based on sales at the drugs' transaction price. (*Id*.)

[4] *See* www.leg.state.nv.us/Statutes/71st/Stats200108.html#Stats200108page1115

36. Northern Nevada and Southern Nevada submit reimbursement claims to Nevada Medicaid, for pharmaceutical drugs used by certain Medicaid patients, that reflect their actual acquisition cost of these drugs. (Ebo Dep. at 87:15-88:9.)[5]

H. Nevada's Responses to Defendants' Interrogatories

37. Pursuant to the Court's September 19, 2006 Order, Nevada filed supplemental responses to Defendants' First Set of Interrogatories and Requests for Production to the State of Nevada ("Defs. Interrogs."), Interrogatory Number Six, which requested Nevada to:

> For each Subject Drug, identify each instance in which a Defendant "marketed the spread" to one or more Providers as alleged in the Complaints, and for each such instance:
> (a) Identify the Manufacturer employee who marketed the spread;
> (b) Identify the Provider to whom the spread was marketed;
> (c) Identify the drug that was marketed;
> (d) Identify the place and time of the alleged marketing; and
> (e) State the manner in which the "spread" was marketed.

(Defs. Interrogs. at 12).

38. Nevada concedes that it lacks any evidence that NPC "marketed the spread' to any Provider.[6] (Third Supplemental Responses of the State of Nevada to Defendants' First Set of Interrogatories (Revised) ("Nev. Resps.") at Ex. A, p. 3.)

[5] Emmanuel Ebo is pharmacy director at Southern Nevada and the statewide pharmacy director at the Mental Health and Developmental Services Division of the Nevada Department of Health and Human Services. (Ebo Dep. at 8:3-17.)

[6] In its response to Interrogatory Number 6, and to Interrogatories Numbers 7 and 8 (see ¶¶ 39-42 below), Nevada states that, "The State cannot provide additional examples at this time because of the limited discovery provided by Novartis." (Nev. Resps., Ex. A at 3; Ex. B at 2; and Ex. C at 3). Nevada never filed a motion to compel against NPC. (Lonergan Aff. at ¶ 15.) Factual discovery in this case is now closed.

39. Pursuant to the Court's September 19, 2006 Order, Nevada filed supplemental responses to Defs. Interrogs., Interrogatory Number Seven, which requested Nevada to:

> For each Defendant, Identify every instance in which You allege such Defendant used discounts, rebates, free goods, charge-backs, and other financial incentives to induce providers to purchase or administer its drugs, as alleged the Complaints, and for each such instance:
>
> (a) Identify the Defendant employee(s) who engaged in such acts;
> (b) Identify the Provider to whom the alleged inducements were directed;
> (c) Identify the drug that was marketed;
> (d) Identify the discounts, rebates, free goods, charge-backs, or other financial
> incentives that were offered; and
> (e) Identify the place and time of the alleged inducement.

(Defs. Interrogs. at 13).

40. Nevada concedes that it lacks any evidence that NPC "used discounts, rebates, free goods, charge-backs, and other financial incentives to induce providers to purchase or administer its drugs." (Nev. Resps., Ex. B, at 2.)

41. Pursuant to the Court's September 19, 2006 Order, Nevada filed supplemental responses to Defs. Interrogs., Interrogatory Number Eight, which requested Nevada to:

> For each Defendant, Identify every instance in which You allege such Defendant has ever made a representation to You concerning the meaning of the term AWP, and every instance where you allege a Defendant has knowingly, willfully, and intentionally concealed its drugs' actual average price from You as alleged in the Complaints, and for each such instance:
>
> (a) Identify what the "actual average price" was;
> (b) Identify the actions of each Defendant that constituted a knowing, willful,
> and intentional concealment; and
> (c) Identify whether that representation was made directly to You.

(Defs. Interrogs. at 13.)

42. Nevada concedes that it lacks any evidence that NPC "made a representation to [Nevada] concerning the meaning of the term AWP" or "knowingly, willfully, and intentionally concealed its drugs' actual average price from [Nevada]." (Nev. Resps. Ex. C, at 3.)

Dated: Boston, Massachusetts
February 8, 2007

Respectfully submitted,

/s/ Karen F. Green

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CERTIFICATE OF SERVICE

I hereby certify that on the 8th day of February, 2007, a true and accurate copy of the Statement of Undisputed Facts in Support of Novartis Pharmaceuticals Corporation's Motion for Summary Judgment was served via the Lexis-Nexis Filing System.

Dated: February 8, 2007

/s/ Brett Budzinski
Brett Budzinski